

**K243509 Archer PSI System**May 12, 2025  
181 days to decisionK243509 · Product code: **QHE** · Orthopedic  
Source: <https://www.510kdatabase.net/k243509/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Arthroplasty Implantation System (QHE)
Date received	Nov 12, 2024
Decision date	May 12, 2025
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3D-Side</b>
Location	Mont-Saint-Guibert, BE
Contact	Florence Allé
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243509/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026